Amendments to the Claims

This listing of claims will replace all prior versions and listings of the claims in the application.

Listing of claims

1. (Currently amended) A solid oral dosage form which includes a composition ~~in solid oral dosage form~~ comprising a drug and, as an enhancer, a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein said composition and each of said constituents and any other constituent comprising the composition is a solid at room temperature.

2. (Cancelled)

3. (Original) The solid oral dosage form of claim 1, wherein the carbon chain length is from 8 to 14 carbon atoms.

4. (Currently Amended) The ~~composition~~ solid oral dosage form of claim 1 wherein the enhancer is a sodium salt of a medium chain fatty acid.

5. (Original) The solid oral dosage form according to claim 4, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.

6. (Original) The solid oral dosage form according to claim 1, wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.

7. (Original) The solid oral dosage form according to claim 6, wherein the polysaccharide is low molecular weight heparin.

8. (Original) The solid oral dosage form according to claim 6, wherein the peptide is luteinising hormone-releasing hormone analog.

9. (Original) The solid oral dosage form according to claim 1, wherein the drug is selected from the group consisting of TRH, unfractionated heparin, insulin, luteinising hormone-releasing hormone (LHRH), leuprolide, goserelin, genotropin, nafarelin, buserelin, alendronate, cyclosporine, calcitonin, vasopressin, desmopressin and salts thereof.

10. (Original) The solid oral dosage form of claim 1, wherein the drug and the enhancer are present in a ratio of from 1:100000 to 10:1 (drug : enhancer).

11. (Original) The solid oral dosage form of claim 1, wherein the dosage form is a tablet, a capsule or a multiparticulate dosage form.

12. (Original) The solid oral dosage form of claim 11, wherein the dosage form is a controlled release dosage form.

13. (Previously presented) The solid oral dosage form of claim 11, wherein the dosage form further comprises a rate-controlling polymer material.

14. (Previously presented) The solid oral dosage form of claim 13, wherein the rate-controlling polymer material is HPMC.

15. (Previously presented) The solid oral dosage form of claim 13, wherein the rate-controlling polymer material is a polymer derived from acrylic or methacrylic acid and their respective esters or copolymers derived from acrylic or methacrylic acid and their respective esters.

16. (Previously presented) The solid oral dosage form of claim 13, wherein the drug and enhancer and at least one auxiliary excipient are compressed into tablet form prior to coating with a rate controlling polymer material.

17. (Original) The solid oral dosage form of claim 12, wherein the drug and enhancer and at least one auxiliary excipient are compressed into tablet form prior to coating with a delayed release polymer.

18. (Previously presented) The solid oral dosage form of claim 13, wherein the drug, the enhancer, the rate-controlling polymer material and at least one auxiliary excipient are compressed to form a controlled release matrix tablet.

19. (Previously presented) The solid oral dosage form of claim 18, wherein the controlled release matrix tablet is coated with a rate-controlling polymer material.

20. (Previously presented) The solid oral dosage form of claim 18, wherein the controlled release matrix tablet is coated with a delayed release polymer.

21. (Previously presented) The solid oral dosage form of claim 13, wherein the drug, the enhancer and at least one auxiliary excipient are compressed into the form of a multilayer tablet prior to coating with the rate controlling-polymer material.

22. (Original) The solid oral dosage form of claim 12, wherein the drug, the enhancer and at least one auxiliary excipient are compressed into the form of a multilayer tablet prior to coating with a delayed release polymer

23. (Original) The solid oral dosage form of claim 13, wherein the drug and enhancer are dispersed in the rate-controlling polymer material and compressed into the form of a multilayer tablet.

24. (Previously presented) The solid oral dosage form of claim 23, wherein the multilayer tablet is coated with a rate-controlling polymer material.

25. (Original) The solid oral dosage form of claim 23, wherein the multilayer tablet is coated with a delayed release polymer.

26. (Original) The solid oral dosage form according to claim 13, wherein the drug, the enhancer, at least one auxiliary excipient, and the rate-controlling polymer material are combined into a multiparticulate form.

27. (Original) The dosage form according to claim 26, wherein the multiparticulate form comprises discrete particles, pellets, minitablets, or combinations thereof.

28. (Original) A solid oral dosage form according to claim 27 comprising a blend of two or more populations of particles, pellets or mini-tablets having different in vitro or in vivo release characteristics.

29. (Original) The dosage form according to claim 26, wherein the multiparticulate is encapsulated in hard or soft gelatin capsules.

30. (Previously presented) The dosage form according to claim 29, wherein the capsule is coated with a rate-controlling polymer material.

31. (Original) The solid oral dosage form according to claim 29, wherein the capsule is coated with a delayed release polymer.

32. (Original) The dosage form according to claim 26, wherein the multiparticulate is incorporated into a sachet.

33. (Original) The dosage form according to claim 27, wherein the discrete particles or pellets are compressed into tablet form.

34. (Original) The dosage form according to claim 33, wherein the tablet form is coated with a rate controlling polymer material.

35. (Original) The dosage form according to claim 33 ,wherein the tablet form is coated with a delayed release polymer.

36. (Original) The dosage form according to claim 27, wherein the discrete particles or pellets are compressed into a multilayer tablet.

37. (Previously presented) The dosage form according to claim 36 wherein the multilayer tablet is coated with a rate controlling polymer material.

38. (Original) The dosage form according to claim 36 wherein the multilayer tablet is coated with a delayed release polymer.

39. (Previously presented) A method of treatment of a medical condition comprising administering orally to a patient suffering from said medical condition a therapeutically effective amount of a dose of a composition which is in solid form and which comprises a drug effective in treating the medical condition and, as an enhancer, a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein said composition and each of said constituents and any other constituent comprising the composition is a solid at room temperature.

40. (Cancelled)

41. (Currently Amended) A process for the manufacture of a composition in solid oral dosage form comprising the steps of:

a) providing a blend of a drug and, as an enhancer: (i) a medium chain fatty acid salt having a carbon chain length of from 6 to 20 carbon atoms; (ii) a medium chain fatty acid halide derivative, medium chain fatty acid anhydride derivative, or medium chain fatty acid glyceride derivative which has a carbon chain length of from 6 to 20 carbon atoms; or (iii)a difunctional medium-chain fatty acid derivative having a carbon chain length of from 6 to 20 carbon atoms, which has on one end ~~a~~ an acid salt, acid halide, acid anhydride, or glyceride derivative of an acid functional group, and on the other end ~~a~~ an acid halide, acid anhydride or glyceride derivative of an acid functional group, or a salt thereof, and which blend also comprises, optionally, another constituent(s), wherein said blend and each of said drug, enhancer, and optional constituent(s) is a solid at room temperature; and

b) forming said solid oral dosage form of the composition from the blend by:

i) direct compression of the blend; or

ii) granulating the blend to form a granulate for incorporation into said solid oral dosage form.

42. (Previously presented) The process according to claim 41 wherein the drug and the enhancer are blended in a ratio of from 1:100000 to 10:1 (drug: enhancer).

43. (Cancelled)

44. (Cancelled)

45. (Cancelled)

46. (Cancelled)

47. (Currently Amended) A composition in solid oral dosage form comprising a drug and, as an enhancer: (a) ~~a~~ acid salt, acid halide, acid anhydride, or glyceride derivative of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, or a salt thereof; or (b) a difunctional medium chain fatty acid derivative which has a carbon chain length of from 6 to 20 carbon atoms, and wherein one functional group is ~~a~~ an acid salt, acid halide, acid anhydride, or glyceride derivative of an acid functional group and the second functional group is an acid halide, acid anhydride or glyceride derivative of an acid functional group, and wherein said composition and each of said constituents and any other constituent comprising the composition is a solid at room temperature.

48. (Cancelled)

49. (Original) The solid oral dosage form according to claim 11, wherein the dosage form is a capsule.

50. (Previously presented) The solid oral dosage form according to claim 49, wherein the capsule is coated with a rate controlling polymer material.

51. (Previously presented) The solid oral dosage form according to claim 49 wherein the capsule is coated with a delayed release polymer.

52. (Previously presented) A dry-blended composition in solid oral dosage form and comprising a drug and, as an enhancer, a salt of a medium-chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.

53. (Previously presented) A solid oral dosage form comprising a drug and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of a salt of a fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.

54. (Previously presented) The solid oral dosage form of claim 53, wherein the enhancer is one or more members selected from the group consisting of a salt of a fatty acid having a carbon chain length of from 8 to 14 carbon atoms.

55. (Previously presented) The dosage form of claim 53 wherein said fatty acid salt is a sodium salt.

56. (Previously presented) The dosage form of claim 55, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.

57. (Previously presented) The dosage form of claim 53, wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.

58. (Previously presented) The dosage form of claim 57, wherein said polysaccharide is low molecular weight heparin.

59. (Previously presented) The dosage form of claim 57, wherein the peptide is luteinising hormone-releasing hormone analog.

60. (Previously presented) The dosage form of claim 53, wherein the drug is selected from the group consisting of TRH, unfractionated heparin, insulin, luteinising hormone-releasing hormone (LHRH), leuprolide, goserelin, genotropin, nafarelin, buserelin, alendronate, cyclosporine, calcitonin, vasopressin, desmopressin and salts thereof.

61. (Previously presented) The dosage form of claim 53, wherein the drug and the enhancer are present in a weight ratio of from 1:100000 to 10:1 (drug : enhancer).

62. (Previously presented) The dosage form of claim 53 selected from the group consisting of a tablet, a capsule, and a multiparticulate.

63. (Previously presented) A method of treatment of a medical condition comprising administering orally to a patient suffering from said medical condition a solid dosage form containing a therapeutically effective amount of a drug effective in treating the medical condition and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of a salt of a fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.

64. (Currently Amended) A process for the manufacture of a solid oral dosage form comprising the steps of:

i) providing a blend of a drug and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of: a) ~~a~~ acid salt, acid halide, acid anhydride, or glyceride derivative of a fatty acid having a carbon chain length of from 6 to 20 carbon atoms; and b) a difunctional fatty acid derivative having functional groups on either end of a carbon chain having a length of from 6 to 20 carbon atoms, wherein the functional groups are selected independently for each occurrence from members of the group consisting of an acid salt, an acid halide, an acid anhydride, and a glyceride functional group, with the provision that both functional groups of said difunctional derivative are not selected to be an acid salt; and

ii) forming said solid oral dosage form of the composition from the blend by:

a) direct compression of the blend; or

b) granulating the blend to form a granular material.

65. (Currrently Amended) A composition in solid oral dosage form comprising a drug and, as the only enhancer present in the dosage form, one or more members selected from the group consisting of:

(a) ~~a~~ acid salt, acid halide, acid anhydride, or glyceride of a fatty acid having a carbon chain length of from 6 to 20 carbon atoms; and

(b) a difunctional fatty acid derivative which has on either end of a carbon chain having a length of from 6 to 20 carbon atoms an acid functional group derivative selected independently for each occurrence from the group consisting of ~~a~~ acid salt, ~~a~~ acid halide, acid anhydride, and a glyceride, with the proviso that both functional groups are not selected to be a salt.

66. (Previously presented) The dosage form of claim 65 wherein the drug, the enhancer, and any other constituent present in the dosage form is a solid at room temperature.